



STATE OF WASHINGTON
WASHINGTON STATE BOARD OF HEALTH
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Minutes – February 25th Genetics Task Force Meeting

The Washington State Board of Health Genetics Task Force (GTF) convened its second meeting on February 25, 2002 at the Phoenix Inn in Olympia, Washington. Linda Lake, Genetics Task Force Chair, called the meeting to order at 9:10 a.m.

Chair Lake introduced the minutes from January 3, 2002 meeting. There was no need to formally adopt the minutes; Chair Lake requested that GTF members let staff know of changes if necessary.

The following Board of Health Genetics Task Force members attended the meeting:

Linda Lake, Chair	Nancy Fisher, M.D., M.P.H., R.N.
Maxine Hayes, M.D., M.P.H.	Vicki Hohner, M.B.A.
Robert Miyamoto	Howard Coleman
Suzanne Plemmons, R.N., M.N., C.S.	Helen McGough
Maureen Callaghan, M.D.	Ty Thorsen
Robin Bennett	Phil Bereano, Ph.D.
Julie Hanna, Ph.D.	Amanda DuBois, J.D.
Melanie Hughes, J.D.	Ree Sailors
Peter Byers, M.D.	

The following Board of Health Genetics Task Force staff attended the meeting:

Don Sloma, Executive Director, Washington State Board of Health
Desiree Robinson, Executive Assistant, Washington State Board of Health
Jennifer Dodd, Assistant, Washington State Board of Health
Candi Wines, Genetics Task Force Coordinator

The following invited speakers attended the meeting:

Jon Hedegard, Rules Coordinator, Office of the Insurance Commissioner
Mary Ferguson, Ph.D., Staff Support

Linda Lake, Chair opened the meeting with a statement of purpose for the meeting. She noted that this meeting is an opportunity for the Genetics Task Force (GTF) to hear evidence of genetic discrimination and genetic privacy violations in Washington State. Prior to the meeting, the Washington State Board of Health staff invited public testimony on evidence of genetic discrimination or privacy violations via task force members, the Washington State Board of Health (BOH) web site, and a news release. Chair Lake stated that evidence of genetic discrimination and privacy violations is necessary in order to make appropriate recommendations. No member of the public requested to testify prior to the meeting nor came forward to testify during the meeting.

JON HEDEGARD - REPORT FROM THE OFFICE OF THE INSURANCE COMMISSIONER

Handouts are available on the BOH GTF website and in the meeting binders.

Questions/Discussion

Dr. Philip Bereano, Task Force Member, in response to Mr. Hedegard's mention of the National Association of Insurance Commissioners (NAIC) study and report, urged the GTF not to rely on the NAIC process. Mr. Hedegard agreed that the process is cumbersome and lengthy and no model regulation or statute exists.

Dr. Bereano brought up the issue that many medical insurance companies claim that they are not asking about genetic information or requiring testing in part because it is too expensive. He asked Mr. Hedegard if he thought that if these procedures were more affordable the current policy and practice would change? Mr. Hedegard indicated that he thought this practice might change especially with respect to life and disability insurance but probably not for health insurance. Dr. Bereano asked Mr. Hedegard to confirm if the statistical tables life insurers use to calculate mortality risks already include risk of genetic disease. Mr. Hedegard indicated that in most cases they do contain calculations that include the risk of genetic disease. Dr. Bereano suggested that therefore life insurers already use genetic information for rate setting and could potentially exclude people who provide the information from coverage.

Dr. Maxine Hayes, Task Force Member, inquired about whether or not there are any statutes in Washington requiring insurers to obtain informed consent for DNA testing? Mr. Hedegard indicated that there were no such laws and suggested this as a possible issue for the GTF to address.

Dr. Bereano asked if there is a means by which the OIC collects information on whether people are discriminated against based on genetic information. Mr. Hedegard said that he can pull relevant documents from the records, but he doesn't believe that information has been systematically collected specifically for that purpose because a problem or question hasn't precipitated that type of survey. Dr. Bereano asked if Mr. Hedegard believed that people were deterred from reporting acts of genetic discrimination by the possibility of retaliation. Mr. Hedegard indicated that he doesn't believe this is a problem, at least he hasn't heard of it. He also indicated that despite direct evidence of such occurrences, it may still be a problem or may become a problem.

Howard Coleman, Task Force Member, inquired about whether the concept of 'asymmetry of information', i.e. if clients start to know more than the insurance company, then insurance companies cannot accurately predict risk, is occurring. Mr. Hedegard said that this does occur and is often seen in the context of life insurance.

NANCY FISHER, M.D., M.P.H., R.N. - HEALTH INSURANCE AND GENETIC INFORMATION IN WASHINGTON: DON'T CONFUSE THE NEWS WITH REALITY!!

[PowerPoint](#) slides are available on the BOH GTF web site and in the meeting binders.

Questions/Discussion

Chair Lake asked Dr. Nancy Fisher, Task Force Member, to clarify her answer to the question on the agenda. Dr. Fisher responded that insurance companies don't look at "genetic information" they look at "medical information". Insurers are concerned with regulations regarding medical information. She noted that specific policies related to genetic information include Regence's policy that genetic testing must be accompanied by genetic counseling and a requirement that pre-natal genetic testing be covered by health insurers in WA State.

Ty Thorsen, Task Force Member, asked if health insurance rates vary between contracts. Dr. Fisher indicated that there are different ways to assign rates. One way is experience rating. Experience rating is based on the history of claims for a group and does not account for specific diagnoses; rather it takes into account the actual services used for a group. Mr. Thorsen asked if different rating plans act as incentives for

an employer to screen employees to get a better rate. Dr. Fisher responded that she doesn't think that can be done.

Dr. Hayes asked if Dr. Fisher would address the issue of how genetic information can be used for rate setting. Dr. Fisher indicated that Mr. Hedegard addressed that question in his presentation. Mr. Hedegard joined the discussion and mentioned that the adjusted community rating is for individuals and small groups but large groups negotiate rates. He doesn't believe that there is an incentive or that employer screening is allowed.

Robin Bennett, Task Force Member, inquired about plans that do not provide payment for genetic testing for specific conditions such as colon cancer in which testing is known to be cost-effective and of clinical significance. Dr. Fisher indicated that there is an appeals process in which patients can request coverage for medically necessary procedures.

Dr. Julie Hannah, Task Force Member, mentioned that genetic tests are often not done as capitated lab work; genetic tests are carved out of the payment schedule. She asked if this exception made genetic tests more vulnerable to scrutiny. She also shared her experience as a physician in which she had been asked to fax genetic test results to an insurance company. She asked what the test result information was used for. Dr. Fisher responded that the information is used only to confirm that the test was done. She noted that the insurance company keeps the test result if they request it because they are required to keep all information but they do not keep it with payment information, it is kept separate. The insurer does not consider what the result was, it used only to confirm that the service was provided. Dr. Fisher stated that genetic tests are sometimes carved out of the payment schedule in laboratory contracts because they are new and expensive and the lab does not yet have the experience to rate them like it does other tests.

Dr. Bereano mentioned that he heard that the insurance industry maintains a computer-based registry. Dr. Fisher indicated that she is not aware of such a registry. Vicki Hohner, Task Force Member, mentioned that there is a Medical Information Bureau. Dr. Bereano asked the staff to look into this database.

Dr. Robert Miyamoto, Task Force Member, asked for clarification regarding whether or not genetic information can be used to set rates even though insurance companies look more at 'medical information' and not specifically at 'genetic information.' Mr. Hedegard responded that several factors are used to set community ratings for small groups: family size, geography, age, activities, and tenure. He is not sure how genetic information would be included in any of these factors. HIPAA regulates large group ratings.

Dr. Fisher suggested that it might not be necessary to create new legislation to protect genetic information; existing laws may already protect it.

Dr. Hayes asked about historical information concerning actual discrimination based on genetic information – is it correct that there are no actual documented cases. Mr. Hedegard indicated that to his knowledge none have been reported to the OIC. Dr. Fisher suggested that people may report 'genetic' discrimination but it really has to do with the underlying medical condition and not the fact that the condition has a genetic component. Dr. Miyamoto made the point that people seek specialized care for genetic disorders and insurance plans may not always cover the specialized care. Dr. Fisher responded that regulations exist regarding genetic tests and appropriate genetic counseling in order to ensure quality of care.

Dr. Maureen Callaghan, Task Force Member, inquired about whether or not insurance carriers have to provide a plan that includes services such as genetic counseling if such a service is required in order to obtain genetic testing.

Chair Lake acknowledged that this may be a form of discrimination, but it is not necessarily on point.

PHIL BEREANO, PH.D. - OVERVIEW OF GENETIC DISCRIMINATION AND GENETIC PRIVACY

Summaries of key court cases and two related articles are available on the BOH GTF website and in the meeting binders.

Dr. Bereano discussed the following key issues:

- No evidence of discrimination is not the same thing as evidence of no discrimination. That we are not aware of any evidence in WA state doesn't mean there isn't any.
- The public is constantly receiving messages that genetics is determinative. The message suggests that genetics is different from other personal information; therefore people are concerned/afraid of how it can be used.
- Even if Washington State has regulations protecting people from health insurance discrimination, it does not mean that life/disability insurance or employment discrimination are prohibited.
- Other states have passed genetic related legislation because it is a big concern to the public. These laws may also be a reason that many companies probably do not use genetic testing. We should not rely on voluntary practices by the industry. Legal standards need to be in place to prevent changes in these policies.
- Previously proposed legislation carved out an exception for researchers. The GTF should address the question of whether such exceptions are justified.
- The GTF should also consider the notion of informed consent any time a DNA sample is taken.

NANCY FISHER, M.D., M.P.H., R.N. - HISTORICAL REVIEW OF GENETIC DISCRIMINATION: EUGENICS

[PowerPoint](#) slides are available on the BOH GTF website and in the meeting binders.

Questions/Discussion

Ms. Bennett mentioned a law in Washington State that forbids cousins from marrying. She expressed that this is an example of genetic discrimination and there is no biological or social reason for this legislation.

Dr. Bereano suggested several publications about genes for specific personality traits. He stated that these publications create many misperceptions. Dr. Fisher recommended web sites for Cold Springs Harbor Laboratory (<http://nucleus.cshl.org/CSHLlib/archives/eugrec.htm> and <http://www.eugenicsarchive.org/eugenics/>) for more information about eugenics.

Ms. Hohner inquired about a relationship between eugenics and patenting. Dr. Peter Byers, Task Force Member, suggested that our society has moved away from eugenics but not really changed the social objectives of the movement, e.g. media don't do a good job at portraying how genetics can be used. Dr. Byers suggested that patenting genes may or may not be an outflow of the eugenics movement, but it is an outflow from a business model.

Dr. Bereano suggested that the patenting issue relates to health care in that it may lead to limited access to health services but patenting laws are a function of federal law and not within the purview of the State. Ms. Hohner clarified that she raised the issue because it is one of privacy.

Ms. Bennett inquired about the committee's role in looking at the marketing of genetic tests. Chair Lake responded that it is not directly related to the GTF's charge but the GTF can outline additional recommendations in the final report.

MARY FERGUSON, PH.D. J.D. (CANDIDATE) - REVIEW OF GENETIC RELATED PRIVACY AND DISCRIMINATION LEGISLATION IN OTHER STATES

[PowerPoint](#) slides and handouts are available on the BOH GTF website and in the meeting binder.

Questions/Discussion

Howard Coleman, Task Force Member, wanted to clarify that employment testing for a genetic predisposition to an environmental exposure is an exception that has been carved out in some legislation. Dr. Mary Ferguson indicated that yes, some states have made exceptions for testing for this purpose.

Dr. Miyamoto asked about the issue of research and genetic privacy, did any state make exceptions for research. Dr. Ferguson indicated that she was not sure if specific states made such exceptions, but proposed federal legislation did include such exceptions and many states modeled their legislation after the proposed federal legislation.

Robin Bennett asked if any states' legislation deals with the issue of adoption. Dr. Ferguson indicated that many states have legislation regarding adoption but she is not sure of the specific details.

Dr. Byers inquired about how the property right is triggered in the states that have it. Dr. Ferguson responded that the right is triggered very early in the process of testing or collecting information.

MARY CLOGSTON - EVIDENCE OF GENETIC DISCRIMINATION AND PRIVACY VIOLATIONS IN WASHINGTON STATE

Handouts are available on the BOH GTF web site and in the meeting binders.

Ms. Clogston noted that the Human Rights Commission has not received any complaints related to genetic discrimination. However, the office believes that the issue is within its scope and that it can adequately address the issue if it arises through existing laws and rules.

Chair Lake dismissed the GTF for lunch at 12:30 p.m. The meeting reconvened at 1:30 p.m.

STAFF ANNOUNCEMENTS

Don Sloma, Executive Director, Washington State Board of Health, gave an update on the status of SB 5207. The bill is currently in the House Committee on Health Care, it was heard in public testimony on Friday 2/22/02. There is a striking amendment on the table to remove everything and insert an expanded definition of DNA with respect to health care information. Chair Lake sent a letter to the Committee stating the Board of Health's position on the bill (a copy was distributed at the GTF meeting). Mr. Sloma testified to the Committee on Friday 2/22/02 and received questions about why the scope of the GTF was so narrow and questions about staying together longer and covering more issues.

Information regarding the bill is available on line at

<http://www.leg.wa.gov/wsladm/billinfo/dspBillSummary.cfm?billnumber=5207>. (Definitions used in the bill are provided in the Genetics Task Force Working Glossary for the April 12, 2002 meeting).

Dr. Hayes raised the issue of storing samples from the Newborn Screening Program. Dr. Bereano asked about the rationale for retaining the samples. Mike Glass, Policy Liaison for Washington State Department of Health Newborn Screening Program, from the NBS responded that the decision to retain the samples is based on laws regulating how long hospitals must retain medical information. A minor's information is retained until the minor reaches the age of 18 plus three years. The Washington State Department of Health (DOH) uses this time frame.

Chair Lake directed the GTF members' attention to a memo and table prepared by Debra Lochner Doyle from the DOH Genetic Services Section. Copies of the memo and table are available on the BOH GTF website and in the meeting binders. Mr. Hedegard from the Office of the Insurance Commissioner (OIC) indicated that he plans to compose a similar document based on information from the OIC.

CANDI WINES - REPORT ON THE EFFECT OF GENETICS PRIVACY LEGISLATION ON RESEARCH

[PowerPoint](#) slides are available on the BOH GTF website and in the meeting binders.

Questions/Discussion

Dr. Bereano made a comment about his specific question of whether or not other states have made an exception for research. He asked if staff or others have found information about this. He also commented on the repeal of the property right provision in the Oregon Genetics Privacy Act. He noted that a property right is an inappropriate way to classify genetic information; it is fundamentally an issue of privacy and genetic information should not be considered a commodity.

Mr. Thorsen inquired about the 'opt out' rule. Candi Wines, Genetics Task Force Coordinator, responded that the opt out rule gave patients/research subjects the opportunity to not allow their samples to be used in anonymous research if the samples were collected after June 2001 when the law went into effect. Samples collected before then are subject to previous requirements. Ms. Wines added that researchers planning to conduct anonymous research in Oregon must submit their proposals to an Institutional Review Board and receive confirmation that the proposed research is actually anonymous. Helen McGough, Task Force Member, mentioned that this is different in Washington where anonymous research is not considered exempt from IRB.

Dr. Byers mentioned the tension between privacy and property as seen from a patient advocacy group perspective. The PXE Foundation made an agreement with families and researchers that some of the monetary benefits received from cloning the gene would go back to the foundation and even back to the families who provided samples for the research. Dr. Byers commented that in light of this, it was hard not to recognize that there is a property issue to consider. Dr. Bereano noted that privacy rights, like property rights, could be waived or used to demand a share in the benefits. Privacy rights give individuals the autonomy to decide what choice to make.

Melanie Hughes, Task Force Member, inquired about the inheritance rights associated with the property rights. Ms. Wines was not sure about the specific details of the application of inheritance rights to the issue, but did remark that the new OR legislation incorporated language that expressed that blood relatives had an interest in a person's genetic information.

Mr. Thorsen inquired about whether the property rights were actually a patent issue. Ms. Wines responded that patent issues may have played a part in the original committee's consideration of the 1995 legislation, but according to one of the drafters it was not the main reason for the clause.

Chair Lake suggested that there needs to be a context for the information presented here and this context may come from the April 12 meeting. Mr. Sloma invited the GTF members to ask their contacts in the research field or biotech industries to get involved in the next meeting. Ms. Bennett suggested that information about the incident at Virginia Commonwealth University might be appropriate to hear at the next meeting. Ms. Lochner Doyle asked for specific questions that the GTF wanted representatives from the biotech industry to address.

DISCUSSION OF GLOSSARY, MATRIX, AND MEETING SUMMARY

Ms. Wines explained the intent and formatting of the glossary, matrix and meeting summary documents. The glossary is an attempt at introducing possible definitions for key terms used by the GTF. The idea behind the matrix is to see where gaps exist in existing legislation. The January 3rd meeting summary is intended to give a synopsis and explanation of issues discussed at the meeting.

Chair Lake invited GTF members to make comments and suggestions regarding the glossary.

COMMENTS ABOUT THE GLOSSARY

GTF members requested that the following terms be added to the glossary: genetic testing, genetic characteristic/trait, anonymous, anonymized, de-identified. Chair Lake recommended drawing a distinction between laws and rules and explaining how changes to each are made.

Chair Lake asked GTF members to email suggestions for revisions or definitions to Candi Wines (candi@nobounds.com).

DISCUSSION OF THE GENETIC INFORMATION PROTECTION MATRIX FOR WASHINGTON

Chair Lake asked the GTF members if there are things to be added to the lists on the left hand side or across the top of the matrix. She also asked the GTF to look within the cells and verify the information.

GTF members recommended the following changes: reformat of the matrix so that it is not divided in to two sections and that all the pertinent laws/regulations are across the top; change title of 'Human Rights Commission' to the 'Washington Law Against Disability' and refer to RCW 49.60 and WAC 162; in the categories on the left, specify what each law regulation protects from; incorporate whether or not the law/regulation specifically defines genetic information into the "encompasses" box; add a category asking if the law/regulation addresses the issue of genetic testing in minor children; add a category asking if the law/regulation controls the use of genetic information in adoption; define 'biological materials'; define 'agencies' as used in the left hand column; change 'No' to 'N/A' or 'does not address' where applicable; specify informed consent requirements under 'IRB oversight' heading; change 'Yes' to 'maybe' under UHCIA in the 'encompasses genetic information' box and in other boxes as appropriate; add box for whether or not there is a penalty for violations.

The GTF held a discussion regarding how genetic information is used in the context of other laws such as marriage (e.g. prohibiting the marriage of cousins). It was not clear that the issue is within the GTF charge, but the GTF agreed to mention it in the final report if appropriate in order to acknowledge that such laws may be discriminatory.

The GTF discussed the issue of how DNA provided for a court case (not by a suspect or criminal in a criminal prosecution case, but in other circumstances) is protected from access by researchers or health care providers/insurers. GTF members requested information about how and where samples are stored and policies regarding retention and destruction in general for samples held outside of the health care system. It was suggested that certain scenarios be generated to see if genetic material or information is protected in each situation.

Chair Lake asked GTF members to review the document in detail and send comments to Candi Wines (candi@nobounds.com).

DISCUSSION OF DIRECTION TO DEVELOP POLICY OPTIONS AND RECOMMENDATIONS

Suggestions on how to proceed included a recommendation to begin thinking about an outline for the final report; a recommendation to reconnect with the legislative staff near the end of deliberations to confirm that the GTF addressed their concerns/questions and met their expectations; a suggestion to identify areas that need attention and policy options; and a suggestion to consider whether or not genetic information is different from health care information in general and therefore does or does not need special protection.

Chair Lake adjourned the meeting at 4:30 p.m. The next GTF meeting is scheduled for April 12, 2002.